IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Plaintiffs, v. MODERNA, INC. and MODERNATX, INC. Defendants.	)	C.A. No. 22-252 (MSG) REDACTED - PUBLIC VERSION Original filing date: January 12, 2024 Redacted filing date: February 2, 2024

LETTER TO THE HONORABLE MITCHELL S. GOLDBERG REGARDING OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL (D.I. 184)

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Dear Judge Goldberg:

Plaintiffs' discovery demands far exceed any sense of reasonable proportionality. After failing in their initial attempt to end-run around Delaware's limit of 10 ESI custodians, D.I. 142, 6:23-8:3, Plaintiffs have not only requested samples from ***all*** batches of Moderna's vaccine, but now also seek (i) ***all*** commercial contracts and sales data, worldwide across the entire company, ignoring the territorial bounds of 35 U.S.C. § 271(a) and (ii) regulatory files from essentially ***every*** IND Moderna has ever filed. But Moderna has already produced its COVID-19 regulatory files and broader R&D documents. Likewise, Plaintiffs' motion regarding Board materials is premature: Moderna ***agreed*** to produce relevant documents provided Plaintiffs do the same. And Moderna has already produced more than 1.35 million pages—as compared to Plaintiffs' production of less than 525,000 pages. Plaintiffs are extreme in their demands, arguing tenuous relevance grounds that in no way justify their ever-expanding requests. Plaintiffs' motion should be denied.

INDs for *All* Products. This case involves ***one*** accused product—Moderna's COVID-19 vaccine—and patents limited to certain lipid formulations. Yet Plaintiffs seek documents from "***all*** [IND] Applications submitted by Moderna to the [FDA] wherein the proposed product comprised LNPs," *i.e.*, essentially every product in Moderna's pre-commercial pipeline, which spans dozens of potential medicines and treatments (*e.g.,* for HIV, cancer, Lyme disease). Ex. A, RFP Nos. 166-167. Plaintiffs' requests defy all bounds of proportionality. And despite having ***no*** asserted claims to manufacturing methods, Plaintiffs, in particular, demand the manufacturing sections in those applications. Mot. at 1; Ex. A, RFP No. 166.

Plaintiffs have the discovery needed for the claims and defenses in this case. Moderna has already complied with arguably overbroad demands for regulatory documents concerning its COVID-19 vaccine: producing more than 400,000 pages of filings, more than 220,000 pages of which comprised the COVID-19 IND.[1] Moreover, at Plaintiffs' insistence, Moderna ran broad terms—hitting on over 300,000 documents—including those related to molar ratios and Moderna's platform, several of which were applied to a decade of ESI from ***all*** 10 custodians, whose responsibilities were not limited to the COVID vaccine. Ex. C, terms III-02 & III-06; Ex. D at 2.

Further discovery into Moderna's unaccused pre-commercial pipeline products is not warranted. First, the unaccused product cases Plaintiffs cite focus almost entirely on discovery to determine whether other products infringe.[2] Plaintiffs admit that is not their goal (nor could it be under the § 271(e)(1) safe harbor), instead arguing that the requested INDs are relevant to copying, willfulness, and/or damages. This is insufficient to establish relevance. *LKQ Corp. v. Gen. Motors Co.*, 2021 WL 4127326, at *1-2 (N.D. Ill. Sept. 9, 2021) (denying discovery into unaccused parts where alleged relevance was "willful infringement because it could show a pattern of copying" and distinguishing from *Invensas*). Second, Plaintiffs cite ***no*** evidence as to what Moderna's other INDs "contain" or "reflect," which is pure speculation. Mot. at 1, 2. Nor do Plaintiffs explain why the INDs would have relevant information that is ***not*** present in the COVID IND. Either Plaintiffs are contending that the requested INDs contain the same relevant information present in the COVID-19 IND—and thus seek duplicative discovery—or Plaintiffs are merely seeking leave for a speculative look through the whole of Moderna's medicines portfolio, which is an insufficient basis to warrant discovery. *Micro Motion, Inc. v. Kane Steel Co.*, 894 F.2d 1318, 1326-28 (Fed.

[1] Yet Plaintiffs refuse to confirm when (or if) they will produce ***a single*** regulatory filing. Ex. B.
[2] The remaining case (*Eli Lilly*) focused on how the unaccused product ***differed*** from the accused product, not discovery into features that could be gleaned from discovery into the accused product.

Cir. 1990); *Ethicon LLC v. Intuitive Surgical*, 2018 WL 1392341, at *3 (D. Del. Feb. 12, 2018); *Hologram USA, Inc. v. Pulse Evolution Corp.*, 2015 WL 13238450, at *4 (D. Nev. Dec. 18, 2015) (denying "*carte blanche* discovery regarding [Defendant's] entire [product] universe"). Plaintiffs' cases regarding "substantial relevance" (*Adv. Display* and *Georgetown Rail*) are inapposite. Neither addresses production of regulatory files, let alone unaccused products.

Plaintiffs' allusion to Moderna's "centralized repository" misses the point. The question of burden rests on what is required to produce the material and must be weighed against relevance. Moderna has ***at least 35 pipeline products*** currently in clinical development, ***each with at least one IND***. Ex. E. Moderna would need to review each document to assign a confidentiality level ***and*** separately confirm whether they contain third-party confidential information requiring third-party notice or consent for production, which Plaintiffs have relied on to refuse discovery. Ex. F at 4 ("obligations of confidentiality"). Plaintiffs cite no precedent for their request for ***all*** of Moderna's INDs. Their (at best) speculative relevance basis cannot justify this undue burden.

OUS Discovery. First, Plaintiffs ignore black-letter law. Courts consistently note the "presumption against extraterritorial application of United States laws." *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 831 F.3d 1369, 1376 (Fed. Cir. 2016) (no direct infringement because OUS products "were neither sold nor offered for sale [] within the United States"); *Cal. Inst. of Tech. v. Broadcom Ltd.*, 25 F.4th 976, 992-93 (Fed. Cir. 2022) ("no dispute that [U.S. infringement] laws apply only domestically"); *Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd.*, 807 F.3d 1283, 1310-11 (Fed. Cir. 2015) (vacating damages for products not made, used in, or imported into U.S.); 35 U.S.C. § 271(a). Plaintiffs do not and cannot deny that activities occurring wholly outside the U.S. ("OUS") are beyond the ambit of U.S. patents. Instead, Plaintiffs argue that their speculation ***alone*** is enough to require Moderna to provide voluminous, burdensome discovery just so Plaintiffs can "test" Moderna's "say-so." Infringement is Plaintiffs' burden. Yet by demanding this production, Plaintiffs are effectively shifting their burden onto Moderna to prove that OUS activity is not actually OUS. Plaintiffs' request is not proportional to the needs of the case. For example, Moderna OUS contracts, REDACTED for which would take months. REDACTED and intervene if warranted. Requiring Moderna to undergo this exercise hundreds of times is a burden that is not outweighed by any likely benefit. If Plaintiffs were correct, every case would open up defendants to worldwide discovery without a shred of evidence indicating that any such "sales" are U.S. sales. Doing so would extend the scope of § 271(a) to "confer a worldwide exclusive right to a U.S. patent holder, which is contrary to the statute and case law." *Halo*, 831 F.3d at 1379.

Second, Plaintiffs' "locus of sale" argument is a distraction. Contrary to Plaintiffs' contention, Moderna ***already*** provided discovery about OUS batches that were subsequently imported into the U.S. as well as U.S. manufactured batches released for distribution abroad. Ex. G; Ex. H. That Plaintiffs do not "accept" "untested assertions" because they have failed to review Moderna's production is not a basis to grant Plaintiffs' extraordinarily broad and irrelevant requests. Nor is their quest for information that objectively cannot be infringement a valid basis. *Kajeet, Inc. v. Qustodio, LLC*, 2019 WL 8060078, at *13 (C.D. Cal. Oct. 22, 2019) (denying motion to compel foreign sales because foreign use of a patented invention "is not infringement at all"); *Tessera, Inc. v. Broadcom Corp.*, 2017 WL 4876215, at *1 (D. Del. Oct. 24, 2017) (denying discovery of foreign core technical documents and worldwide sales because plaintiff "needs to

show that its request is premised on more than 'mere suspicion or speculation'").[3]

Third, Plaintiffs' ever-shifting positions on OUS discovery is untenable. Ex. 11, Ex. 14; Ex. I; Ex. G. After loosely raising the issue in May, Plaintiffs ignored it until November. Ex. 11 at 11; Ex. J at 4; Ex. P at 6. Then Plaintiffs pivoted from seeking all OUS analytical data to all OUS contracts so that they could "assess" whether additional information about OUS batches should be produced by Moderna. Ex. 11 at 1. Later, Plaintiffs stated that they were entitled to "discovery about whether sufficient activities surrounding the sale occurred" within the U.S. Ex. 14 at 4. These shifting positions are the definition of a fishing expedition. *Apex Fin. Options, LLC v. Gilbertson*, 2021 WL 5206104, at *2 (D. Del. Nov. 9, 2021). Plaintiffs' requests concerning sales and samples of Moderna's COVID-19 vaccine wholly manufactured and used OUS should be denied.

Board Materials. This unripe dispute should be denied—Moderna has not refused to produce Board documents. Moderna offered to "produce non-privileged Board documents which reference lipid molar ratios in the Accused Product or refer to the Asserted Patents" if Plaintiffs agree to produce the same. Ex. 15 at 2. Plaintiffs "responded" to this good faith offer with this premature motion. Indeed, ***just one day*** before filing, Plaintiffs for the first time confirmed that they possess Board documents, indicating both parties were still investigating these requests.[4]

Moderna offered a scope of documents focused on issues relevant to this litigation—the lipid molar ratio of the Accused Product (the subject of the Asserted Patents). Contrary to Plaintiffs' assertions, Moderna has disputed the relevance of the full scope of RFP No. 130 because it essentially demands ***all*** Moderna's Board documents and relates to ***all*** aspects of Moderna's COVID-19 vaccine (its only commercially available product), "not all of which are relevant to damages or infringement." Ex. O at 2. For example, clinical trial information is irrelevant because the asserted claims are not to methods of use. The production of all Moderna's Board documents is burdensome, and courts have denied such broad requests. *Osucha v. Alden State Bank*, 2020 WL 3055790, *6 (W.D.N.Y. June 9, 2020) (limiting production to documents that "mention plaintiff by name or clearly refer to plaintiff in all but name"). Moderna proposed a compromise to reduce scope and burden which Plaintiffs ignored—permitting relevance redactions for Board documents—***despite Plaintiffs' own position that they intend to redact for relevance and sensitivity in certain circumstances***. Ex. F at 2. To the extent the Court orders the parties to produce certain Board Materials, courts have permitted redactions of irrelevant "commercially or scientifically sensitive information," *Holley v. Gilead Scis., Inc.*, 2020 WL 2097602, at *3 (N.D. Cal. May 1, 2020), and Moderna would request such redactions be permitted here.

Moderna respectfully requests that the Court deny Plaintiffs' Motion to Compel.

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[3] Plaintiffs' cases are inapposite. *McGinley*, 2018 WL 9814589, at *5 (involvement "in many aspects of the sales between foreign manufacturers and foreign distributors" was relevant to whether sales occurred in U.S.); *Apeldyn*, 2010 WL 11470585, at *1 (excuse that "it does not know where its products go is not good enough to avoid the production of documents"); *Positive Techs.*, 2013 WL 707914, at *4 (denying protective order barring discovery of sales information for non-accused accessories and services sold with accused e-readers on the basis of convoyed sales).

[4] Moreover, ***Plaintiffs and Roivant have likewise refused to produce Board documents requested by Moderna***, including documents related to the Asserted Patents that are highly relevant. Roivant is not a disinterested third-party as Plaintiffs suggest; it REDACTED [redacted] Ex. K at 5; Exs. L-N.

Respectfully,

/s/ Travis J. Murray

Travis J. Murray (#6882)

TJM:lo
Enclosures
cc: All Counsel of Record (via CM/ECF and electronic mail)